



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2016-0438; FRL-9953-44-OW]

### **Request for Public Comments to be sent to EPA on Peer Review Materials to Inform the Safe Drinking Water Act Decision Making on Perchlorate**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of request for public comment.

**SUMMARY:** The U.S. Environmental Protection Agency (EPA) is announcing the release of materials for public comment that will undergo expert peer review in support of the EPA's Safe Drinking Water Act decision making on perchlorate. This request is one of two Federal Register notices being published concurrently, seeking public comment on two separate sets of peer review materials. The Agency requests comment on both the draft Biologically Based Dose-Response Model and an accompanying draft model report entitled "Biologically Based Dose-Response Models for the Effect of Perchlorate on Thyroid Hormones in the Infant, Breast Feeding Mother, Pregnant Mother, and Fetus: Model Development, Revision, and Preliminary Dose-Response Analyses." These materials will be reviewed by an expert peer review panel and the panelists will consider the public comments received. A companion notice published on this date requests comments on the interim list of peer reviewers and draft peer review charge questions to be sent to EPA's contractor, Versar, Inc.

**DATES:** Comments on the draft Biologically Based Dose-Response (BBDR) model and draft report must be received by EPA on or before **[45 days after publication in the Federal Register]**.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-OW-2016-0438, to the Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the online instructions

for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:** For additional information concerning the draft BBDR model and the draft report, please contact Russ Perkinson at U.S. EPA, Office of Ground Water and Drinking Water, Standards and Risk Management Division, (Mail Code 4607M), 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone: 202-564-4901; or e-mail: [perkinson.russ@epa.gov](mailto:perkinson.russ@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Information on EPA's Biologically Based Dose-Response (BBDR) Model for Perchlorate in Drinking Water**

EPA has begun development of a national primary drinking water regulation (NPDWR) for perchlorate, in accordance with the requirements of the Safe Drinking Water Act (SDWA). One statutory requirement is that the Agency must request comment from EPA's Science Advisory Board (SAB) prior to proposal of a maximum contaminant level goal (MCLG) and a NPDWR.

In 2012, EPA sought guidance from the SAB on how best to consider and interpret life stage information, epidemiologic and biomonitoring data, physiologically-based pharmacokinetic (PBPK) analyses and the totality of perchlorate health information to derive an MCLG for perchlorate.

In 2013, the SAB recommended that, “. . . EPA derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling based upon its mode of action rather than the default MCLG approach using the reference dose and specific chemical exposure parameters” (Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate, EPA-SAB-13-004).

Based on the SAB’s recommendations, EPA, with contributions from Food and Drug Administration scientists, developed a BBDR (also known as a PBPK/PD) model. The BBDR model was developed by integrating PBPK models for perchlorate and iodide with BBDR models for thyroid hormones to predict the effect of perchlorate on the thyroid gland in formula-fed and breast-fed infants for the postnatal period from days 7 to 90, as well as lactating women. The draft model is focused on the condition of hypothyroxinemia as an indicator of the potential adverse health effects. This integrated draft model predicts the effects of perchlorate on serum thyroid hormone concentrations in the pregnant and lactating mother exposed to perchlorate in the diet and in infants exposed via ingestion of perchlorate in formula or breast milk.

## **II. How to Obtain the Draft BBDR Model and Draft Reports**

EPA’s draft model report entitled “Biologically Based Dose Response Models for the Effect of Perchlorate on Thyroid Hormones in the Infant, Breast Feeding Mother, Pregnant Mother, and Fetus: Model Development, Revision, and Preliminary Dose-Response Analyses” is available electronically and can be accessed using the Public Docket at

<http://www.regulations.gov> (Docket ID No. EPA-HQ-OW-2016-0438). The draft BBDR model code files can be accessed at

[https://hero.epa.gov/hero/index.cfm/reference/details/reference\\_id/3352518](https://hero.epa.gov/hero/index.cfm/reference/details/reference_id/3352518). All written comments must be submitted during the public comment period.

### **III. Exclusion for Peer Review Candidates**

Important: Anyone wishing to be considered as an expert peer reviewer must not submit comments during the public comment period. Candidates on the interim list not selected for the panel peer review (see companion Peer Review Federal Register notice, published on **[INSERT DATE of publication in the Federal Register]**) will be given a limited opportunity to submit public comments once the final peer reviewers are selected by Versar, Inc., the EPA contractor managing this peer review process.

Dated: September 23, 2016.

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Office of Water.

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